

K0 53328

JAN 25 2006

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**Section III - SMDA Summary of Safety and effectiveness – “510(K) Summary”**

1. Submitter Information:

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Date summary prepared: November 25<sup>th</sup>, 2005

2. Device name

Trade Name: **BIOSPLINT Splinting ribbon**  
Common/Usual Name: Dental Splinting ribbon  
Classification Name: Dental / Resin, denture, Relining, Repairing, Rebasing,  
per 21 CFR §872.3760

3. Devices for which Substantial Equivalence is claimed:

- RIBBOND (RIBBOND Inc) K913040 dated 10/07/1991
- CONNECT (SYBRON DENTAL SPECIALITIES Inc) K954689 dated 10/30/1995

#### 4. Device description:

##### PRESENTATION

Box containing:

- 8 ribbons (Braided polyethylene terephthalate fibers) individually wrapped in aluminium bags (width: approximately 2.5 mm - length: approximately 50 mm - thickness: ~ 0,15 mm).
- Accessories: BIOSPLINT™ Thermal cutter, BIOSPLINT™ Accessories: brushes and probes

##### PROPERTIES

BIOSPLINT™ Splinting ribbons are fixed to the teeth using a light curing flowable hybrid composite and a one-bottle light-curing adhesive system. BIOSPLINT™ Splinting ribbons are treated using the so-called "super-critical fluid" process. This treatment is a process for "cleaning" the fibers, allowing to improve the impregnation of the fiber by the composite and thus to improve the cohesion of the overall tooth retention system

BIOSPLINT™ Splinting ribbons can be pliable in order to be adapted to the curves of the teeth. Their low thickness makes it possible to avoid any oral embarrassment after setting in place.

BIOSPLINT™ Splinting ribbons can remain in place for several years if necessary; in this case a regular monitoring of the patient is necessary.

#### 5. Intended use of the Device

BIOSPLINT™ Splinting ribbons are used for Stabilization of mobile teeth, Temporary replacement of missing teeth, Maintain of inter-dental spaces, Reinforcement or repairing of temporary or permanent bridges.

#### 6. Substantial Equivalence:

The BIOSPLINT™ Splinting ribbon is substantially equivalent to other legally marketed devices in the United States: CONNECT and RIBBOND are intended for a similar use.

## 7. Efficacy of the Device

The efficacy of the use of this kind of device is well established in the professional literature since 1992 (GOLDBERG AJ, BURSTONE CJ, "The use of continuous fiber reinforcement in dentistry" dent.mater 1992; 8:197-202).

The BIOSPLINT™ Splinting ribbon has been successfully used in Europe since 1997.

The following articles concerning their efficacy in clinical practice have been published in French professional literature:

- **«Provisional mandibular contention, : interest of BIOSPLINT - About a clinical case»**

N.KOUBI and G. ABOUDHARAM - G.KOUBI Chairman of university Marseilles France

Information dentaire n° 1 du 5 janvier 2000 p 11-19

- **«Uses of fibers reinforced composite in dentistry »**

BIJAOUI J. - SIMON A.L. - TIRLET G. René DESCARTES University PARIS 5 -France

Les cahiers de l'ADF N°10 - 4<sup>ème</sup> trimestre 2000

- **« A new material for an esthetic contention : polyethylenephtalate fibers »**

OUHAYOUN J.P. and BENALIKHOJJA M. University of Garancière PARIS 7 -France

Information dentaire n° 9 du 28 février 2001 p 569-578

- **«Temporary replacement of unit tooth in implantology : polymere ribbon and flowable composite»**

OUHAYOUN J.P. University of Garancière PARIS 7 -France

Alternatives n° 26 de mai 2005 p 45-49

The mechanical and esthetic properties of these kinds of fibers enhance the use of these products in the recommended clinical situations. Copies of listed articles are available upon request.

## 8. Safety of the Device

The BIOSPLINT™ Splinting ribbon is controlled according to the specifications presented in Appendix D.

BIOSPLINT™ Splinting ribbon comply to the following tests:

- **AMES test,**

*Method:* according to guidelines O.C.D.E.n° 471 (1981) - EEC 84/449 - annex V - method B14 (1984) - ref: study n° 104E201E

*Results and conclusion:* According to the experimental conditions described, the flat fibers ref FTEKRU1950 has no mutagenic effect against TA-98, TA-100, TA-1535, TA-1537 and TA-1538 strains without metabolic activation.

- **Pyrogenes test,**

*Method:* according to the French Pharmacopoeia - ref: study n° 104E201A

*Results and conclusion:* comply

- **Sensitization test** on guinea pigs

*Method:* according the method described in the Annual book of ASTM standards F 619-79- ref: study n° 104E201D

*Results and conclusion:* According to the experimental conditions described (extract prepared at 37 °C during 120 hours with 0.9 % sodium chloride solutions), the fibers are not sensitizing.

- **Intramuscular implantation** on the rabbit,

*Method:* according to USP XXII - ref: study n° 104E102

*Results and conclusion:* comply

- **Toxicity by systemic injection** on the mouse

*Method:* according to USP XXII on extracts prepared at 50°C during 72 hours with 0.9 % sodium chloride solutions, 5 % alcohol solutions, gingili oil and polyethylene glycol 400 solutions. - ref: study n° 104E102

*Results and conclusion:* comply

- **Intradermal injection** on the rabbit

*Method:* according to USP XXII on extracts prepared at 50°C during 72 hours with 0.9 % sodium chloride solutions, 5 % alcohol solutions, gingili oil and polyethylene glycol 400 solutions. - ref: study n° 104E102

*Results and conclusion:* comply

- **Biocompatibility evaluation**

*Method:* implantation test on the rabbit (adaptation of ASTM F 763-87, F 981-87 and ISO 10993-6) was performed with a semi-quantitative histological study of the tissue response after 1, 4, 12, 26 and 52 weeks - ref: study n° 104E203

*Results and conclusion:* the macroscopical and histopathological observations did not show any local adverse effect which can be due to the fiber.

- **in-vitro Cytotoxicity**

*Method:* according to USP XXIII - elution test (incubation 48 hours, 37 °C, 5% CO<sub>2</sub>)

*Results and conclusion:* not cytotoxic

*Test results available upon request.*



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

JAN 25 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SATELEC  
C/O Mr. Steven Salesky  
Regulatory Affairs  
Acteon, Incorporated  
130 Gaither Drive, Suite 100  
Mount Laurel, New Jersey 08054

Re: K053328  
Trade/Device Name: BIOSPLINT Splinting Ribbons  
Regulation Number: 872.3760  
Regulation Name: Denture Relining Repairing or Rebasing Resin  
Regulatory Class: II  
Product Code: EBI  
Dated: November 29, 2005  
Received: December 1, 2005

Dear Mr. Salesky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Salesky

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known):

K053328

Device Name:

**BIOSPLINT Splinting ribbons**

Indications For Use:

**Stabilization of mobile teeth**

**Temporary replacement of missing teeth**

**Maintain of inter-dental spaces**

**Reinforcement or repairing of temporary or permanent bridges**

Please refer to the attached file for a complete description.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

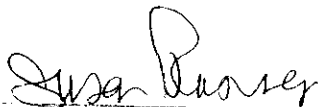
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Concurrence of CDRH, Office of Device Evaluation (ODE)



Division of Small Business  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number

K053328

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